

# **EXHIBIT 22**

Safe Use and Handling Card

The card below is an important reminder of what you should do to keep yourself, your family, and others safe while you are taking opioid pain medicine. Tear or cut the card out along the dotted line and keep it for quick reference.

Tear Out Along Edge

This card contains important reminders to help ensure the safe use, handling, and disposal of your opioid pain medicine.

DO

- Read the Medication Guide
- Take exactly as prescribed
- Take exactly as it was given to you
- Call 911 in case of accidental use or overdose

DO NOT

- Do not take with alcohol
- Do not take with medicines that make you sleepy
- Do not drive unless safe to do so

Copyright © 2010 All rights reserved.

My Meds Card

Complete the "My Meds Card" below, tear or cut out the card along the dotted line, and keep it in your wallet for handy reference whenever you see your healthcare provider or pharmacist.

Tear Out Along Edge

**My Meds Card**

Name: \_\_\_\_\_ Phone #: \_\_\_\_\_

My Pain Doctor: \_\_\_\_\_ Phone #: \_\_\_\_\_

My Pharmacy: \_\_\_\_\_ Phone #: \_\_\_\_\_

Date	Drug Name	Dose	How Much (pills / day)	Why I Take It

Copyright © 2010 All rights reserved.

FOLD

To learn more about how you can help improve patient safety and reduce the risk of prescription pain medications, call us at 1-800-233-8969 or visit our Web site:

[www.caresalliance.org](http://www.caresalliance.org)

C.A.R.E.S Alliance was created to help patients, healthcare professionals, nonprofit organizations and people in the pharmaceutical industry work together to improve patient safety.

Provided as an educational resource by C.A.R.E.S. Alliance

COVIDIEN, COVIDIEN with logo and Covidien logo are U.S. and internationally registered trademarks of Covidien AG. C.A.R.E.S. Alliance is a service mark of Mallinckrodt Inc. © 2010 Covidien. CA-100 November 2010. Printed in USA.

COVIDIEN  
675 McDONNELL BLVD  
HAZELWOOD, MO 63042  
[WWW.COVIDIEN.COM](http://WWW.COVIDIEN.COM)

Opioid Safe Use and Handling Guide

A Resource for Patients

CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

MNK-T1\_0003416495

## Key Terms

- **Abuse** - Use of a medication for a nonmedical purpose such as altering one's state of consciousness (ie, getting high).
- **Addiction** - A disease in which people crave or cannot control use of a drug, or continue using a drug even though they know it is not good for them.
- **Misuse** - Use of a medication prescribed for a legitimate medical purpose in ways other than as directed or indicated.
- **Opioid** - A kind of medication that is often used to treat pain. Opioids are very strong medicines that are dangerous if used in ways other than as directed or by people who do not have a prescription.
- **Opioid Tolerance** - A change in your body from taking opioid pain medicine for a period of time, causing one or more effects of the medicine to be reduced. For example, tolerance may mean you have to take more opioid pain medicine to get the same pain relief. Tolerance is not the same as addiction.
- **Overdose** - A life-threatening state that occurs when a person takes more of a medication than his or her body can handle.

## Table of Contents

Introduction.....	2
Understanding the Risk of Overdose .....	3
Understanding the Risk of Abuse.....	5
Understanding the Risk of Addiction .....	7
Talking With Your Healthcare Provider.....	8
How to Protect Yourself and Your Family .....	9
Examples of Extended-Release and Long-Acting Opioids .....	11
Glossary of Important Terms.....	12
References .....	13
Safe Use and Handling Card .....	15
My Meds Card .....	16

## Introduction

Your healthcare provider has determined that an **opioid** analgesic (strong pain reliever) is an appropriate medicine to treat your pain. Before you start taking this medicine, you should understand how to safely use and handle opioid pain medicines so that the benefits outweigh the risks.

This document does not take the place of speaking to your healthcare provider or reading the product Medication Guide. The Medication Guide contains the most important safety information. Always read the Medication Guide that accompanies your medicine.





## Understanding the Risk of Overdose

Opioid analgesics are strong pain medicines that can cause life-threatening breathing problems, and some opioids can cause life-threatening heart problems. If prescribed and used correctly, opioid pain medicines can be safely used to manage your pain. However, if used in any way other than as instructed by your healthcare provider or if used by a person for whom they were not prescribed, these medicines can cause an overdose that could lead to life-threatening breathing problems.

### Quick Facts

- ✦ Accidental use by a child is a medical emergency and can result in death.<sup>1-3</sup> If a child accidentally takes opioid pain medicine, get emergency help right away, even if the child is not experiencing any side effects
- ✦ Taking opioid pain medicine when it has not been prescribed to you can cause an overdose and lead to life-threatening breathing problems, especially in children<sup>1</sup>
- ✦ Thousands of people die each year due to overdose as a result of prescription opioid **abuse** or **misuse**<sup>4</sup>
- ✦ An **overdose** can occur if opioid pain medicine is not taken properly<sup>1, 2, 5</sup>



## Tips to Prevent Overdose

- ✦ Take your opioid pain medicine exactly as prescribed or directed<sup>1, 2, 5</sup>
- ✦ Do not take more than your prescribed daily dose<sup>1-3, 5</sup>
- ✦ Never use alcohol while taking opioid pain medicines<sup>1-3, 5</sup>
- ✦ Ask your healthcare provider before you take other medicines<sup>1-3, 5</sup>
- ✦ Keep opioid pain medicines in a safe place away from children and from anyone for whom they have not been prescribed<sup>1-3, 5</sup>
- ✦ Never share your opioid pain medicine
- ✦ Dispose of your opioid pain medicine as soon as it is no longer needed<sup>6, 7</sup> (See Safe Disposal, p. 10)
- ✦ Call 911 immediately in case of overdose or accidental use

## Special Considerations for Extended-Release Opioids\*

- ✦ Many pain medicines should be taken only if you are already regularly using opioid pain medicines around the clock and your body is used to taking these medicines. This means you are **opioid tolerant**.<sup>1-3, 5</sup> If you have any questions talk to your healthcare provider or pharmacist
- ✦ Certain, usually extended-release, opioid pain medicines should only be taken for long-term pain and should not be used to treat pain that you have only once in a while or that is expected to last for only a short time<sup>1-3, 5</sup>
- ✦ Do not break, chew, crush, or dissolve tablets or capsules that are meant to be swallowed whole, do not snort, inject, or inhale tablet or capsule contents, and do not use opioid patches other than as directed<sup>1-3, 5</sup>
- ✦ Talk to your healthcare provider if you have any questions and to ensure that your opioid medicine is right for you

\*See page 11 for examples of some extended-release and long-acting opioid pain medicines.

# Understanding the Risk of Abuse

Opioid pain medicines can be a target for people who abuse prescription medicines or street drugs.<sup>1,2,5</sup> Keep your opioid pain medicine in a safe place to prevent abuse or theft,<sup>1</sup> especially by people you live or work with or who come into your home or workplace. Most people, including children, who abuse opioid pain medicines get them from friends or family members.<sup>8</sup>

## Quick Facts

- ◆ More than 30 million Americans aged 12 years or older report having used prescription opioids nonmedically in their lifetime. More than 2 million people 12 years and older begin abusing prescription opioids every year<sup>8</sup>
- ◆ Individuals aged 12 and older who abuse prescription opioids report that the majority of the time they obtain the drug from a friend or relative either for free, by purchasing it, or by stealing it<sup>8</sup>
- ◆ A recent survey of teenagers, grades 7-12, found that 40% of all teens believe prescription medicines, even if they are not prescribed by a doctor, are safer to use than illegal drugs. One in three teens believes that prescription pain relievers are not addictive<sup>9</sup>
- ◆ Individuals who have problems with other drugs like alcohol or marijuana are more likely to abuse prescription opioid pain medicine



## Tips to Prevent Abuse

- ◆ Keep your opioid pain medicine in a safe place to prevent abuse or theft<sup>5</sup>— especially by people you live or work with or who come into your home or workplace
- ◆ Keep opioid pain medicines in a safe place away from children and from anyone for whom they have not been prescribed<sup>1-3,5</sup>
- ◆ Properly dispose of your opioid pain medicine as soon as it is no longer needed<sup>6,7</sup> (see Safe Disposal, p. 10)
- ◆ Discuss your home environment with your healthcare provider to evaluate your home for risk factors for abuse and overdose
- ◆ Tell your healthcare provider if you are concerned that someone close to you at home or at work may steal or use your medicine

## Evaluate Your Home for Environmental Risk Factors for Abuse and Overdose

- ◆ Presence of young children
- ◆ Presence of adolescents or young adults
- ◆ Presence of any person, including friends, relatives, or strangers, who may have
  - A history of substance abuse or **addiction** (eg, alcohol, marijuana)
  - A history of drug-seeking behaviors
  - Mental health issues such as depression or anxiety
- ◆ Improper medicine handling, storage, or disposal (see How to Protect Yourself and Your Family, p. 9)







## How to Protect Yourself and Your Family

You are responsible for using your opioid pain medicine safely and keeping it away from family members, friends, household acquaintances, and anyone else who does not have a prescription.

Follow the steps below to protect yourself and your family.

### Keep Away From Children

- Store opioid pain medicines in a child-proof container<sup>6</sup>
- Never transfer your opioid pain medicine into an uncontrolled container like a daily pill reminder<sup>6</sup>

### Keep Away From Others

- Limit access to your opioid pain medicine to yourself or your caregiver only<sup>6</sup>
- Do not share your opioid pain medicine with someone else, even if they have the same symptoms as you<sup>1-3, 5</sup>
- Never sell or give away your opioid pain medicine to anyone. It is against the law, and it may harm them<sup>1-3, 5</sup>

### Protect From Theft

- Protect your opioid pain medicine from theft at all times<sup>1</sup>
- Always keep your opioid pain medicine secured or locked up and out of reach of children<sup>6</sup>
- Keep a regular count of the number of remaining pills

### Safe Disposal

- Properly dispose of your opioid pain medicine as soon as you and your healthcare provider decide you no longer need it<sup>6, 7</sup>
- To dispose of unused oral opioid pain medicine, remove the medicine from the bottle or package and flush it down the toilet<sup>1-3, 5, 6, 13</sup>
- To dispose of fentanyl transdermal patches, open the unused patches, fold the sticky sides of the patches together, and flush them down the toilet<sup>3</sup>





## Examples of Extended-Release and Long-Acting Opioids

Extended-release and long-acting opioids are opioid pain medicines that usually work for 8-24 hours. These medicines are typically for patients who experience pain continuously throughout the day (around the clock).

Trade Name	Generic Available	Generic Available
Duragesic®	Fentanyl Transdermal System	Yes
EXALGO®	Hydromorphone HCl Extended-Release Tablets	No
Dolophine®	Methadone HCl Tablets	Yes
Methadose™	Methadone HCl Tablets	Yes
EMBEDA®	Morphine Sulfate + Naltrexone HCl Extended-Release Capsules	No
AVINZA®	Morphine Sulfate Extended-Release Capsules	Yes
KADIAN®	Morphine Sulfate Extended-Release Capsules	Yes
MS Contin®	Morphine Sulfate Controlled-Release Tablets	Yes
Oramorph®	Morphine Sulfate Sustained-Release Tablets	Yes
OxyContin®	Oxycodone HCl Extended-Release Tablets	Yes
OPANA® ER	Oxymorphone Extended-Release Tablets	No

Data accurate as of 8/18/2010.

## Glossary of Important Terms

**Abuse:** Use of a medication for a nonmedical purpose such as altering one's state of consciousness (ie, getting high).

**Acute Pain:** A normal sensation triggered in the nervous system to alert you to possible injury and the need to take care of yourself.<sup>14</sup>

**Addiction:** A disease in which people crave or cannot control use of a drug, or continue using a drug even though they know it is not good for them.<sup>10</sup>

**Around-the-Clock Opioid Pain Medicine:** Opioid pain medicine (usually extended-release opioids) taken regularly throughout the day (around the clock) to provide continuous pain relief.<sup>15</sup>

**Breakthrough Pain:** A sudden, brief flare of moderate-to-severe pain that "breaks through" the relief provided by around-the-clock opioid pain medicine.<sup>16</sup>

**Chronic Pain:** Pain that lasts for more than 3 months.

**Extended-Release and Long-Acting Opioids:** Opioid pain medicines for patients who experience chronic pain continuously throughout the day (around the clock). These medicines usually work for 8–24 hours.

**Misuse:** Use of a medication prescribed for a legitimate medical purpose in ways other than as directed or indicated.

**Opioid:** A kind of medication that is often used to treat pain. Opioids are very strong medicines that are dangerous if used in ways other than as directed or by people who do not have a prescription.

**Opioid Tolerance:** A change in your body from taking opioid pain medicine for a period of time, causing one or more effects of the medicine to be reduced.<sup>10</sup> For example, tolerance may mean you have to take more opioid pain medicine to get the same pain relief. Tolerance is not the same as addiction.<sup>10</sup>

**Overdose:** A life-threatening state that occurs when a person takes more of a medication than his or her body can handle.



**Physical Dependence:** A condition in which you become sick if you suddenly stop taking your opioid pain medicine because your body has gotten used to it.<sup>10</sup> Physical dependence is not the same as addiction.<sup>10</sup>

**Pseudoaddiction:** Drug-seeking behavior that appears similar to addiction but is due to a need for more medication to control pain rather than addiction.

**Short-Acting/Normal Release Opioid:** A kind of medicine that usually works for about 2 to 6 hours.

**References:** **1.** EXALGO Medication Guide. Hazelwood, MO: Mallinckrodt Brand Pharmaceuticals; 2010. **2.** EMBEDA Medication Guide. Bristol, TN: King Pharmaceuticals, Inc.; 2009. **3.** Duragesic Medication Guide. Raritan, NJ: Ortho-McNeil-Janssen Pharmaceuticals, Inc.; 2009. **4.** US Center for Disease Control Issue Brief: *Unintentional Drug Poisoning in the United States*. [http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/brief\\_full\\_page.htm](http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/brief_full_page.htm). Accessed July 27, 2010. **5.** OxyContin Medication Guide. Stamford, CT: Purdue Pharma LP; 2009. **6.** FENTORA Medication Guide. Frazer, PA: Cephalon Inc.; 2007. **7.** ONSOLIS Medication Guide. Somerset, NJ: Meda Pharmaceuticals Inc.; 2009. **8.** US Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. *Results from the 2008 National Survey on Drug Use and Health: national findings*. <http://www.oas.samhsa.gov/2k8nsduh/2k8Results.pdf>. Accessed May 23, 2010. **9.** Partnership for A Drug-Free America. *Partnership Attitude Tracking Study [PATs]*. 2006. [http://www.drugfree.org/files/full\\_teen\\_report](http://www.drugfree.org/files/full_teen_report). Accessed June 17, 2010. **10.** American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine. Definitions related to the use of opioids for the treatment of pain. <http://www.painmed.org/pdf/definition.pdf>. Accessed May 23, 2010. **11.** Fleming MF, Balousek SL, Klessig CL, Mundt MP, Brown DD. Substance use disorders in a primary care sample receiving daily opioid therapy. *J Pain*. 2007;8(7):573–582. **12.** Fishman SM. *Responsible opioid prescribing: A physician’s guide*. Washington, DC: Waterford Life Sciences; 2007. **13.** <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely>. Accessed June 30, 2010. **14.** The American Academy of Pain Management. *Facts and Figures on Pain*. <http://www.painmed.org/patient/facts.html#pain>. Accessed June 30, 2010. **15.** Simon S. Opioids and treatment of chronic pain: understanding pain patterns and the role for rapid-onset opioids. *MedGenMed*. 2005 Nov 23;7(4):54. **16.** Portenoy RK and Hagen NA. Breakthrough pain: definition and manifestations. *Primary Care Cancer*. 1991 April;27–28,33.

Safe Use and Handling Card

Tear Out Along Edge

You are responsible for keeping your opioid pain medicine away from anyone who could be harmed by using it inappropriately or taking it accidentally.

Follow these steps to protect yourself and others:

- Keep away from children
- Keep away from others
- Keep in a safe, secure place, and protect from theft
- Dispose of properly

My Meds Card

Tear Out Along Edge

This card is provided as an important aid in ensuring that your opioid pain medicine is right for you. You should carry this card with you every time you see your healthcare provider or pharmacist.

**Take this card with you every time you see your pharmacist.**

- Record all of your medications in the space provided
- Never opt out of pharmacy counseling
- Read the Medication Guide you get with every opioid pain medicine prescription

FOLD

1. To make sure your pain medicine is right for you, tell your doctor your complete medical and family history, including any history of substance abuse or mental illness

• All medications you take, including over-the-counter (non-prescription) medicines, vitamins, and dietary supplements

• The cause, severity, and nature of your pain

• Any side effects you may be having

• Changes in your home environment

• Your treatment goals

2. Take your opioid pain medicine with you to every office visit

3. Take your opioid pain medicine exactly as prescribed by your health care provider

FOLD